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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,535	10/12/2005	Josef Prassler	MS027US	8828
81777	7590	11/03/2009	EXAMINER	
MorphoSys AG			VOGEL, NANCY TREPTOW	
Lena-Chris-Str				
48			ART UNIT	
Martinsried, 82152			PAPER NUMBER	
GERMANY			1636	
			NOTIFICATION DATE	
			DELIVERY MODE	
			11/03/2009	
			ELECTRONIC	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

salmutter@morphosys.com  
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### Office Action Summary

**Application No.**

10/522,535

**Applicant(s)**

PRASSLER ET AL.

**Examiner**

NANCY VOGEL

**Art Unit**

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 September 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/CI/CD)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date 4/6/09

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 9/3/09 has been entered.

### ***Information Disclosure Statement***

Applicant has stated that the Information Disclosure Statement filed 4/26/09 has not been considered by the Examiner, and requests the Examiner to do so. A copy of said Information Disclosure Statement is attached.

### ***Priority***

Regarding priority, applicants state that the PAIR does not identify the priority claim to US application serial number 60/399,150 filed on July 30 2002. However, in the PALM system and on the Bibliographic Data Sheet available to the Examiner and included in this Office action as an attachment, this document is identified.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohning (US2002/0034733) in view of Burger et al. (Appl. Microbiol. Biotechnol. (1999) 52:345-353).

Lohning disclose phagemid vectors [0010] comprising a prokaryotic promoter (Fig. 16a) , a first nucleic acid sequence encoding an immunoglobulin-presenting polypeptide, which may be the phage coat protein gIII [0015] or fragment thereof [0017], a second nucleic acid sequence encoding a first Ig polypeptide, and a third nucleic acid sequence encoding a second Ig polypeptide [0050]. See Figs. 6a, 7a, 16a. A first and second associating agent are fused to or comprised within said Ig-presenting polypeptide and the first Ig polypeptide [0008, 0009, 0010]. The reference discloses that the first and second Ig polypeptides self-associate to form a Fab or other functional Ig fragment, via non-covalent interactions [0156]. The reference discloses that the first and second associating agents associate with each other via disulfide bond, and is a cysteine residue [0054]. The reference discloses prokaryotic secretory signal sequences in the same reading frame as each of the nucleic acid sequences [0156-0157]. The associating agents would become disassociated in solution upon the addition of a reducing agent [0070]. The vector comprises a ribosome binding site positioned 5' to the nucleic acid sequence encoding each of the first, second and third

polypeptide, since it is shown in the reference that proteins are produced using the disclosed expression vectors, and therefore at least one ribosome binding site is present in the normal, 5' region of the start site of the polypeptide encoding region. The reference exemplifies the use of two vectors, with one encoding the Ig presenting polypeptide pIII, and a bicistronic vector encoding the heavy and light chain, with each comprising a signal sequence upstream of the coding region, wherein the resultant Fab is linked to the pIII protein via disulfide bond (Example 2.2). The difference between the reference and the instant claims is that a single tricistronic vector carrying all components is not disclosed.

However, tricistronic vectors are known in the art as disclosed by Burger et al. Burger et al. disclose tri-cistronic vectors to achieve stable expression and/or secretion of three polypeptides of interest, two of which are Ig polypeptides (light chain and heavy chain). The reference discloses that a tricistronic vector is useful for "providing stability of expression which is a critical requirement for industrial scale production" (page 351). It would have been obvious to one of ordinary skill in the art to have used a tricistronic vector, as disclosed by Burger et al., to express the genes disclosed by Lohning, since both references are concerned with the expression of three different gene products simultaneously in an expression system. One would have been motivated to do so by the disclosure of Burger et al. of the usefulness of such vectors for obtaining stability of expression of three gene products. Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Applicants have argued in their response filed 9/3/09 that the rejection should be withdrawn, since Burger et al. had difficulties in expressing two structural proteins using the disclosed tricistronic vector, and Burger et al. used the tricistronic vector for a "completely different purpose than the present application, the creation of a cell line for large scale production", and therefore there is no motivation to combine the references. Applicants point to page 348 of Burger et al. to support the argument that there were difficulties encountered in the expression of only two structural polypeptides, and puromycin acetyltransferase, which is an enzyme that allows selection due to puromycin resistance. However, while Burger may have disclosed that there were difficulties encountered, it remains that Burger et al. was successful in the expression of three proteins. The fact that one of the proteins was not a "structural" protein as opposed to an enzyme, does not obviate the fact that Burger et al. succeeded in using a tricistronic vector for the expression of three encoded proteins or enzymes. Furthermore, applicants argue that Burger et al. used the tricistronic vector for a completely different purpose, since their goal was the production of a high yield, stable cell line, as opposed to a phage display of proteins. However, it is maintained that the high expression of the encoded three proteins was a common goal in both Burger et al. and the instant application, and the fact that different proteins were encoded does not teach away from the combination of the references. One of ordinary skill in the art would have recognized that a vector for the expression of any particular proteins, would be applicable to the expression of different proteins, since gene expression using any particular vector is well known in the art. Based upon the teachings of the cited

references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention. Therefore, the rejection is maintained.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

10/26/09  
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